

Appl. No. 10/043,344
Reply to Office Action of October 15, 2004

Remarks/Arguments:

According to the Office Action, mailed October 15, 2004 (hereinafter, "*Office Action*"), claims 14 and 18 to 27 are currently pending and under examination. In the *Office Action*, the Examiner made the following objections and rejections:

- Objection to the disclosure for informalities.
- Objection to claim 24 for reference to tables.
- Claim Rejections – 35 USC § 112, first paragraph.
- Claim Rejections – 35 USC § 112, second paragraph.
- Obviousness-Type Double Patenting.
- Claim Rejections – 35 USC § 102(b).
- Claim Rejections – 35 USC § 103(a).

1. **Remarks:**

a. **Response is timely.**

A response to the *Office Action* was due on January 13, 2005. The applicants attach hereto a Petition For Extension Of Time Under 37 CFR 1.136(a) along with payment of the associated fee. With the 3-month extension of time to respond to the *Office Action*, a response becomes due on April 13, 2005. This response was filed before this date and is therefore timely.

b. **Fees.**

The applicants attach hereto a completed Credit Card Payment Form for the fee associated with the Petition For Extension Of Time Under 37 CFR 1.136(a). The applicants do not believe that any additional fees are due. However, please charge any additional fees required or credit any fees overpaid to Deposit Account No. 50-0244.

c. **Amendments to the Specification.**

Without prejudice or disclaimer, the specification was amended by replacing the paragraph beginning on page 1, line 11 to update the status of the U.S. Application No. 08/649,518. This amendment applies to the paragraph earlier amended by applicants by their Preliminary Amendment, dated January 11, 2002.

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Without prejudice or disclaimer, the specification was amended by replacing the paragraph beginning on page 44, line 6 to update the most current address for the American Type Culture Collection.

No new matter was added by the above amendments.

d. Amendments to the Claims.

Claims 14, and 18 to 24 were canceled without prejudice or disclaimer.

Claim 25 was amended without prejudice or disclaimer and to further Applicants' business interests and the prosecution of the present application.

The amendment to claim 25 is supported in the specification at page 8, line 21 to page 9 to line 19.

The amendment to claim 25 does not add any new matter. Applicants reserve the right to prosecute any canceled or amended subject matter in a later application.

2. Arguments.

a. Objection to the specification for informalities.

The disclosure at page 44 was objected to for informalities because the address of the American Type Culture collection is no longer correct. (*Office Action*, page 2). The applicants amended the disclosure at page 44 so that this address is correct. Accordingly, the applicants respectfully request that this objection be withdrawn.

b. Objection to claim 24 for reference to tables.

Claim 24 was objected to because the claim relies on Table 2 and 3 of the disclosure. (*Office Action*, page 3). The applicants canceled claim 24, and, therefore, the objection is moot.

c. Claim Rejections – 35 USC § 112, first paragraph.

Claims 14 and 18-27 were rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement. (*Office Action*, page 3). The Examiner alleges that the written description in the instant case only sets forth specific amino acid sequences and does not disclose a particular portion of the protein or analogs of the transferrin receptor protein, and, therefore the written description is not commensurate in scope with the claims drawn to portions or analogs of the transferrin receptor protein. The Examiner

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further alleges that neither the specification nor the claims teach how to define the portions or analogs; neither the claims nor the specification teach how to obtain such portions or analogs; and there is no guidance as to what portions or analogs are, or what portions or analogs can or cannot be used in the immunogenic composition being claimed. The applicants respectfully traverse this rejection.

The applicants canceled claims 14 and 18-24; and, therefore, the rejection as to these claims is moot. The applicants amended claim 25 so that it is directed to a genus of immunogenic compositions comprising at least one synthetic peptide having no less than six amino acids and no more than 150 amino acids and a pharmaceutically acceptable carrier therefor; wherein the synthetic peptide is comprised of the amino acid sequence, LEGGFYGP (SEQ ID NO: 74) or LEGGFYG (SEQ ID NO: 85), and produces an immune response when administered to a host. Amended claim 25 no longer contains the terms "portions" or "analogs" of a transferrin receptor protein.

The MPEP at §2163, subsection I, in pertinent part, states:

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116.

The MPEP at §2163, subsection II,3(a),ii, in pertinent part, states:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, ...reduction to drawings, ...or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

Page 63, lines 15-27 of the instant application states:

This Example illustrates the synthesis of synthetic peptides corresponding to conserved regions in Tbp2 and Tbp1.

The deduced amino acid sequences of Tbp1 and Tbp2 were compared as shown in FIGS. 14 and 15 respectively. This comparison identified regions of amino acid sequence conservation within the transferrin receptor described above and, as shown in Tables 2 and 3, peptides were synthesized containing a portion of the transferrin receptor. Such synthesis may be effected by expression in a suitable host of recombinant vectors containing nucleic acid encoding said peptides or by standard peptide synthesis.

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Table 3 of the instant application (at page 76) shows 4 synthetic peptides (SEQ ID Nos: 50, 61, 74 and 85) which were synthesized which have amino acid sequences which contain no less than six amino acids and no more than 150 amino acids and each of which is comprised of the amino acid sequence, LEGGFYGP (SEQ ID NO: 74) or LEGGFYG (SEQ ID NO: 85). Table 4 of the instant application (at page 78) shows that one of these synthetic peptides (i.e., SEQ ID No: 50) when made part of an immunogenic composition produces an immune response when administered to a host. In view of the sufficient description of a representative number of species by actual reduction to practice provided in the instant application, the applicants contend the invention claimed in claims 25-27 are described in sufficient detail so that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention; and, therefore, the claims comply with the written description requirement of 35 USC § 112, first paragraph. Accordingly, the applicants respectfully request that this rejection be withdrawn.

Claim 23 was rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement. (*Office Action*, page 5). The rejection is said to be a deposit rejection.

Applicants canceled claim 23; and, therefore, the rejection as to this claim is moot.

d. Claim Rejections – 35 USC § 112, second paragraph.

Claims 14 and 18-27 were rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter the applicant regards as the invention. (*Office Action*, page 8). The Examiner alleges the limitation in claim 14, "said at least one active component", lacks an sufficient antecedent basis. The Examiner also alleges that claim 14 is vague and confusing because it is unclear what is meant by the phrase, "...corresponding to a portion of a transferrin receptor protein of a strain or of an analog..."; the term "analog" is vague because it is not unclear what proteins or peptides would or would not be considered analogs; and the phrase "at least one active component" is unclear because it is unclear what components are intended to be included in this composition.

The applicants canceled claims 14 and 18-24; and, therefore, the rejection as to these claims is moot.

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The applicants amended claim 25 so that it no longer depends on claim 14; and, by this amendment claims 26 and 27 no longer indirectly depend on claim 14 to which the rejection is directed. Accordingly, the applicants contend that claims 25-27 comply with the written description requirement of 35 USC § 112, first paragraph. Accordingly, the applicants respectfully request that this rejection be withdrawn.

e. Double Patenting.

Claims 14, 18-19 and 24-27 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,922,562 in view of Loosmore et al. WO 96/40929. (*Office Action*, page 9).

The applicants respectfully request that the Examiner hold the above obviousness-type double patenting rejection in abeyance until allowable subject matter has been agreed upon. At that time, the applicants will file the appropriate terminal disclaimer.

f. Claim Rejections – 35 USC § 102(b).

Claims 14 and 18-22 were rejected under 35 USC § 102(b) as being anticipated by Holland et al. (*Office Action*, page 12).

The applicants canceled claims 14 and 18-22; and, therefore, the rejection as to these claims is moot.

g. Claim Rejections – 35 USC § 103(a).

Claims 24-27 were rejected under 35 USC § 103(a) as being unpatentable over Schryvers (U.S. Patent No. 5,141,743 in view of Gerlach et al. The Examiner indicated that these claims are drawn to an immunogenic composition comprising SEQ ID NO: 74. (*Office Action*, 14).

The Examiner characterizes Schryvers as teaching the isolation and purification of transferrin receptor proteins from bacterial pathogens and vaccines containing transferrin receptor proteins, where the transferrin receptors in human pathogens can be from *Neisseria* species, *Haemophilus influenzae* and *Branhamella catarrhalis* (col. 4 lines 47-64); as teaching a transferrin receptor vaccine comprising a transferrin receptor protein isolated from a bacterium or organism expressing the protein, or a synthetic peptide whose amino acid sequence is based on the amino acid sequence of a purified transferrin receptor protein, or the nucleotide sequence of a cloned receptor (col. 3 lines 57-68); and as teaching a preparation of transferrin receptor protein,

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synthetic peptide or nucleotide sequence of a cloned receptor may be suspended in a reagent and include an adjuvant (col. 4, lines 1-5). However, the Examiner admits that Schryvers does not teach the use of SEQ ID NO: 74 as being comprised within the immunogenic composition.

The Examiner characterizes Gerlach et al. as teaching that several bacteria including *Actinobacillus pleuropneumoniae*, *Netssera* species, *Haemophilus Influenzae* and *Pasturella haemolytica* all use the transferrin of their host as their only source of iron (page 3253); as teaching the ability to use the host iron correlates with the binding of transferrin by iron-starved cells; as teaching the cloning of a gene encoding transferrin binding protein from *A. pleuropneumoniae* along with other analogous genes from several different serotypes of *A. pleuropneumoniae* (page 3253), the nucleotide sequence of this gene, the deduced amino acid sequence of the transferrin-binding protein; and the amino acid sequence, SEQ ID No: 74, as part of the deduced amino acid sequence.

Having characterized Schryvers and Gerlach et al., the Examiner reasons that it would have been *prima facie* obvious at the time of applicants' invention to have used known synthetic peptides within an immunogenic composition and modify the composition to include the SEQ ID NO: 74 because Gerlach et al. teach that it is well known in the art to make and use immunogenic composition comprising SEQ ID NO: 74 as the synthetic peptide and a pharmaceutically acceptable carrier with at least one active component producing an immune response when administered to a host. Additionally, the Examiner reasons that as the transferrin peptide sequences are well known in the art to induce an immune response, one would have a reasonable expectation of success since no more than routine skill would have been required to use a peptide when the art teaches that immunogenic compositions containing synthetic peptides are known in the art to invoke an immune response in a host and even be protective, and no more than routine skill would have been required to modify the well known composition by simply incorporating alternative and equivalent antigenic products for the purpose of inducing an immune response in a subject. The applicants respectfully traverse this rejection.

The examiner has the burden to establish a *prima facie* case of obviousness by establishing three basic criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination

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and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

As noted above, the applicants amended claim 25 so that it is directed to an immunogenic composition comprising at least one synthetic peptide having no less than six amino acids and no more than 150 amino acids and a pharmaceutically acceptable carrier therefor, wherein the synthetic peptide is comprised of the amino acid sequence, LEGGFYGP (SEQ ID NO: 74) or LEGGFYG (SEQ ID NO: 85), and produces an immune response when administered to a host. As claims 26-27 are dependent on claim 25, the arguments below directed to claim 25 apply equally to claims 26-27.

The applicants respectfully submit that the Examiner has not met her burden to establish a *prima facie* case of obviousness, as discussed below.

i. No suggestion or motivation to combine reference teaching.

The applicants respectfully submit that there is no suggestion or motivation, either in Schryvers and Gerlach et al. themselves or in prior art, to modify these references or to combine their teachings to arrive at the claimed invention.

The references cited by the Examiner at most suggest combining these references to arrive at a composition comprising peptide of a transferrin receptor protein of *Actinobacillus pleuropneumoniae* where the peptide has an unspecified amino acid sequence. Neither Schryvers nor Gerlach et al. suggest or motivate the modification of the other so that the unspecified peptide comprises the amino acid sequence, LEGGFYGP (SEQ ID NO: 74) or LEGGFYG (SEQ ID NO: 85), and would produce an immune response when administered to a host. Figure 2 of Gerlach et al. shows the deduced amino acid sequence of an *Actinobacillus pleuropneumoniae* (serotype 7 isolate) transferrin binding protein which consists of 547 amino acids and contains the amino acid sequence LEGGFYGP (SEQ ID NO: 74) within it. However, the teaching of Schryvers does not modify this figure so that a synthetic peptide having no less than six amino acids and no more than 150 amino acids and comprising the amino acid sequence, LEGGFYGP (SEQ ID NO: 74) or LEGGFYG (SEQ ID NO: 85) is arrived at. Likewise, Figure 4 of Gerlach et al. shows the deduced amino acid sequence of an *Actinobacillus pleuropneumoniae* (serotype 1 isolate) transferrin binding protein which consists of 593 amino acids and contains the amino acid sequence LEGGFYGP (SEQ ID NO: 74) within it. However, the teaching of Schryvers does not modify this figure so that a synthetic peptide having

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no less than six amino acids and no more than 150 amino acids and comprising the amino acid sequence, LEGGFYGP (SEQ ID NO: 74) or LEGGFYG (SEQ ID NO: 85) is arrived at.

With respect to what was known in the prior art, the limitations of the claimed invention of defined size for a synthetic peptide and that the peptide comprise the amino acid sequence, LEGGFYGP (SEQ ID NO: 74) or LEGGFYG (SEQ ID NO: 85) arose from discoveries made by the applicants and are not found in the prior art. This is made manifest in the disclosure of the instant application at page 23, line 3 through page 25, line 33:

The amino acid sequences of Tbp1 from *H. influenzae* strains Eagan/Minna, DL63, PAK 12085 and SB33 strains are compared in FIG. 14. The Tbp1 proteins of Eagan and Minna are identical and 912 amino acids in length, that of DL63 has 914 residues, that of PAK 12085 has 914 residues, and that of SB33 has 911 residues. The *H. influenzae* Tbp1 proteins are highly conserved with 95-100% sequence identity. The amino acid sequences of Tbp2 from *H. influenzae* strains Eagan/Minna, DL63, PAK 12085 SB12, SB29, SB30 and SB32 are compared in FIG. 15. The Tbp2 proteins of Eagan and Minna are identical and contain 660 amino acids, that of DL63 has 644 residues, and that of PAK 12085 has 654 residues. There is a single base deletion in the SB33 *tbp2* gene which results in a frame-shift at residue 126 and premature truncation of the resulting protein at residue 168. The missing base was confirmed by direct sequencing of PCR amplified chromosomal DNA. With the exception of Eagan and Minna which are identical, the Tbp2 protein sequences are less conserved with only 66-70% identity, but there are several short segments of conserved sequence which can be identified in FIG. 15. The PCR amplified *tbp2* genes from strains SB12, SB29, SB30 and SB32 were all found to encode full-length Tbp2 proteins. There was sequence and size heterogeneity amongst the deduced Tbp2 proteins wherein SB12 had 648 amino acids, SB29 had 631 residues, SB30 had 630 residues and SB32 had 631 residues.

Putative secondary structures of Eagan Tbp1 and Tbp2 were determined (FIGS. 16A and 16B). Both proteins have several transmembrane domains, with Tbp1 traversing the membrane 20 times and Tbp2 crossing it 12 times. Three exposed conserved epitopes were identified in the Tbp1 amino-terminal region (DNEVTGLGK - SEQ ID NO: 43, EQVLN/DIRDLTRYD - SEQ ID NOS: 139 and 140, and GAINEIEYENVKAVEISK - SEQ ID NO: 141) and one in the C-terminal region (GI/VYNLF/LNYRYVTWE - SEQ ID NOS: 142 and 143). Only three small conserved regions can be identified within the Tbp2 proteins of the human pathogens: CS/LGGG(G)SFD - SEQ ID NOS: 75, 144 and 145 at the N-terminal, LE/SGGFY/FGP - SEQ ID NOS: 74 and 146 located internally, and VVFGAR/K - SEQ ID NOS: 83 and 84 at the C-terminus. The discovery that the Tbp2 amino acid sequence varies between strains of *Haemophilus* allows for the grouping of *Haemophilus* into sub-groups defined by the same Tbp2 amino acid sequence. This discovery allows the rational selection of a minimal number of Tbp1 and/or Tbp2 sequences or synthetic peptides representing epitopes shared by such subtypes within strains of *Haemophilus* to be used in immunogenic compositions for, for example, immunization against the diseases caused by *Haemophilus* and other bacteria that produce transferrin receptor with sequence

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similarities to Tbp1 and Tbp2 from *Haemophilus* species. Thus, a minimal number of transferrin receptor, analogs, fragments, and/or peptides, may be used to immunize against many or all strains of *Haemophilus* and other bacterial pathogens that produce transferrin receptor.

Furthermore, the amino acid sequences of the transferrin receptor from a range of bacterial pathogens (*H. influenzae* type b, non-typable *H. influenzae*, *Neisseria meningitidis*, *Neisseria gonorrhoeae* and *Actinobacillus (Haemophilus) pleuropneumoniae*) were compared as shown in FIGS. 14 and 15. This analysis revealed regions of Tbp1 and Tbp2 which are conserved between all of these bacteria. Some of such conserved sequences are contained in peptides in Tables 2 and 3. In particular the sequences DNEVTGLGK (SEQ ID: 43), EQVLNIRDLTRYPGI (SEQ ID NO: 44), EQVLNIRDLTRYPGISVVEQG RGASSGYSIRGMD (SEQ ID NO: 45), GAINEIHYENVKAVEISKG (SEQ ID NO: 46) and GALAGSV (SEQ ID NO: 47) are conserved in Tbp1 (Table 1 and FIG. 14). Particular conserved sequences in Tbp2 include LEGGFYGP (SEQ ID NO: 74), CSGGGSFD (SEQ ID NO: 75), YVYSG (SEQ ID NO: 76), CCSNLSYVKFG (SEQ ID NO: 77), FLLGHRT (SEQ ID NO: 78), EFNVOF (SEQ ID NO: 79), NAFTGTA (SEQ ID NO: 80), VNGAFYG (SEQ ID NO: 81), ELGGYF (SEQ ID NO: 82), VVFGAR (SEQ ID NO: 83) and VVFGAK (SEQ ID NO: 84) (Table 2 and FIG. 15).

The discovery of conserved sequences within the transferrin receptor of a range of bacterial pathogens allows the selection of a minimal number of antigens having particular amino acid sequences (including in the form of synthetic peptides) to immunize against the disease caused by pathogens that have transferrin receptors. Such bacteria in addition to those recited above include other species of *Neisseria*, such as *Neisseria gonorrhoeae*, and *Branhamella*, including *Branhamella catarrhalis*. Such conserved amino acid sequences among many bacterial pathogens permits the generation of Tfr specific antibodies, including monoclonal antibodies, that recognize most if not all transferrin receptors. Antiserum was raised against peptides corresponding to conserved portions of the transferrin receptor. This antiserum recognized the transferrin receptor in *Branhamella catarrhalis*. Such antisera are useful for the detection and neutralization of most if not all bacteria that produce Tfr protein and are also useful for passive immunization against the diseases caused by such pathogens. Diagnostic assays and kits using such conserved amino acid sequences are useful to detect many if not all bacteria that produce transferrin receptor. [underlines added for emphasis]

Finally, the applicants are uncertain if the Examiner intended to cite Figure 1 of Gerlach et al. as this figure shows physical maps of certain plasmids.

The Examiner alleges, in part, that Gerlach et al. teach that it is well known in the art to make and use immunogenic composition comprising SEQ ID NO: 74 as the synthetic peptide and that such peptide would produce an immune response when administered to a host. The applicants respectfully request that the Examiner cite the relevant portion of Gerlach et al. to support this allegation, as applicants are unable to identify where it is taught that it is well known in the art to make and use immunogenic composition comprising SEQ ID NO: 74 as the

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synthetic peptide and that this peptide would produce an immune response when administered to a host.

ii. No teaching or suggestion of all the claim limitations.

The applicants respectfully submit that combination of Schryvers and Gerlach et al. do not teach or suggest all of the claim limitations of the claimed invention.

Schryvers does not teach or suggest any specific synthetic peptide, and, in particular, a peptide comprising the amino acid sequence, LEGGFYGP (SEQ ID NO: 74) or LEGGFYG (SEQ ID NO: 85). Instead, the reference generally mentions that a transferrin receptor vaccine antigen comprising a preparation which can be synthetic peptide whose amino acid sequence is based on the amino acid sequence of a purified transferrin receptor protein or a nucleotide sequence of a cloned receptor gene. (Col. 3, lines 65-69). Moreover, this reference does not teach or suggest a specific peptide which produces an immune response when administered to a host. Gerlach et al. does not teach or suggest a synthetic peptide having no less than six amino acids and no more than 150 amino acids. Instead, Gerlach et al. teach two transferrin binding proteins (not peptides) having an amino acid sequence consisting of 547 or 593 amino acids. Even if, for the sake of argument, these proteins were taken to be peptides, neither would be a synthetic peptide having no less than six amino acids and no more than 150 amino acids. Moreover, this reference does not teach a peptide of these transferrin receptor proteins produces an immune response when administered to a host.

iii. No reasonable expectation of success.

The applicants respectfully submit that there is no reasonable expectation of success of arriving at the claimed invention based on the teaching of Schryvers and Gerlach et al. or in the prior art.

As mentioned above, Schryvers does not teach or suggest any specific synthetic peptide or a peptide comprising the amino acid sequence, LEGGFYGP (SEQ ID NO: 74) or LEGGFYG (SEQ ID NO: 85); it generally mentions that a transferrin receptor vaccine antigen comprising a preparation which can be synthetic peptide whose amino acid sequence is based on the amino acid sequence of a purified transferrin receptor protein or a nucleotide sequence of a cloned receptor gene. (Col. 3, lines 65-69). Also, as mentioned above, Figures 2 and 7 of Gerlach et al. teaches the deduced amino acid sequence of a *Actinobacillus pleuropneumoniae*, serotype 1 and 7 isolates, respectively, transferrin binding protein which

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consists of 547 or 593 amino acids, respectively, and each protein contains the amino acid sequence LEGGFYGP (SEQ ID NO: 74) within it, but does not teach a synthetic peptide having no less than six amino acids and no more than 150 amino acids and comprising the amino acid sequence, LEGGFYGP (SEQ ID NO: 74) or LEGGFYG (SEQ ID NO: 85). Moreover, the reference does not teach a peptide produces an immune response when administered to a host. As neither Schryvers and Gerlach et al. teach all of the limitations of the claimed invention, one of ordinary skill in the art at the time of filing the instant application would have no guidance to arrive at a synthetic peptide having no less than six amino acids and no more than 150 amino acids; wherein the synthetic peptide is comprised of the amino acid sequence, LEGGFYGP (SEQ ID NO: 74) or LEGGFYG (SEQ ID NO: 85), and which produces an immune response when administered to a host.

The Examiner alleges, in part, that as the transferrin peptide sequences are well known in the art to induce an immune response, one would have a reasonable expectation of success at arriving at the claimed invention since no more than routine skill would have been required to use a peptide in a composition, and no more than routine skill would have been required to modify the well known composition by simply incorporating alternative and equivalent antigenic products for the purpose of inducing an immune response in a subject. The applicants respectfully request that the Examiner cite the relevant portions of Schryvers or Gerlach et al. or other prior art to support these allegations, as the applicants are unable to identify where it is taught in these references or in the prior art that synthetic peptides of a transferrin receptor protein are well known in the art to produce an immune response when administered to a host.

3. Conclusions.

The amendments, remarks, and arguments submitted herein are intended to be fully responsive to the outstanding Office Action, to advance the prosecution of the present invention, and to place the application in condition for allowance.

The applicants respectfully request consideration and entry of this paper. The applicants also respectfully request reconsideration of this application, as amended, and issuance of a timely Notice of Allowance in this case. Should the Examiner have any questions concerning this application, she is invited to contact the undersigned at (570) 839-5537.

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